Celltrion USA and Prometheus Laboratories Inc. Announce Sponsored Testing Collaboration on Anser® IFX for ZYMFENTRA® (infliximab-dyyb)

Celltrion Testing Access Program Expands Availability of Therapeutic Drug Monitoring to Support Patient Transition to Subcutaneous Infliximab

JERSEY CITY, N.J., and SAN DIEGO, Calif., July 6, 2026 – Celltrion USA ("Celltrion") and Prometheus Laboratories Inc. ("Prometheus") today announced a sponsored collaboration to provide access to Anser® IFX therapeutic drug monitoring (TDM) services for patients eligible to receive ZYMFENTRA® (infliximab-dyyb), the first and only FDA-approved subcutaneous infliximab for the maintenance treatment in adults with moderately to severely active ulcerative colitis and moderately to severely active Crohn's disease following intravenous (IV) infliximab.

Through the Celltrion Testing Access Program, eligible patients may receive access to Anser IFX testing to help clinicians evaluate and optimize infliximab therapy as patients transition from IV to subcutaneous administration for maintenance treatment. Anser IFX testing, with its expanded upper limit of quantitation, is designed to support the higher drug concentrations commonly observed with subcutaneous infliximab dosing and provide actionable insights into drug levels and antidrug antibodies.

Bincy Abraham, MD, MS, Director of the Underwood Center - Fondren Inflammatory Bowel Disease Program commented, "Therapeutic drug monitoring is standard of care when treating inflammatory bowel disease patients with infliximab. Expanding access to Anser IFX testing for subcutaneous infliximab enables clinicians to make informed decisions and aligns with our mission to help our patients achieve and maintain remission in a timely and accessible manner."

The sponsored testing program is designed to reduce barriers to therapeutic drug monitoring and provide clinicians with timely, objective data to support treatment decisions, including evaluating appropriate candidates for transition to subcutaneous maintenance therapy.

"This collaboration underscores Celltrion's commitment to improving patient access to innovative therapies and supporting providers with tools that enhance treatment decision-making," said Randy Ermert, Vice President, Strategic Accounts at Celltrion USA. "By enabling broader access to therapeutic drug monitoring, we aim to help clinicians optimize treatment for patients transitioning to ZYMFENTRA, offering an efficacious, durable, self-administered maintenance option."

"At Prometheus, we are dedicated to advancing precision medicine through clinically actionable insights," said Patricia Vasquez, President at Prometheus Laboratories. "By expanding access to Anser IFX testing, this collaboration helps providers better understand drug exposure and immunogenicity, supporting confident treatment transitions and improved patient outcomes."

About Celltrion USA
Celltrion USA is Celltrion's US subsidiary established in 2018. Headquartered in New Jersey, Celltrion USA is committed to expanding access to innovative biologics to improve patient care for US patients. Celltrion's portfolio includes FDA-approved biosimilar products in immunology, oncology, hematology, and endocrinology. Celltrion USA will continue to leverage Celltrion's unique heritage in biotechnology,

supply chain excellence and best-in-class sales capabilities to improve access to high-quality biopharmaceuticals for US patents. For more information, please visit celltrionusa.com and stay updated on our latest news and events on our social media: LinkedIn.

About Prometheus Laboratories Inc.
Prometheus Laboratories is a leading specialty clinical laboratory which improves the healthcare journey for individuals with immune-mediated and gastrointestinal diseases by empowering providers to diagnose, treat and help get their patients into remission faster with precision-guided care. For more information, please visit prometheuslabs.com and engage with us on LinkedIn.

About Anser IFX
Anser IFX is part of a family of proprietary homogenous mobility shift assays used to optimize biologic and biosimilar therapy in autoimmune diseases. The test simultaneously measures biologic drug and antidrug antibody levels in serum and was recently validated to expand the upper limit of quantitation in support of testing for subcutaneous infliximab. Anser testing was first launched in 2012 and has been the subject of over 100 peer-reviewed publications and abstracts. Over 500,000 Anser tests have been performed for more than 230,000 unique patients.

About ZYMFENTRA® (infliximab-dyyb)
ZYMFENTRA® (infliximab-dyyb) is a prescription medicine used as an injection under the skin (subcutaneous injection) by adults for the maintenance treatment of moderately-to-severely active ulcerative colitis following treatment with an infliximab product given by intravenous infusion (IV), moderately-to-severely active Crohn's disease following treatment with an infliximab product given by intravenous infusion (IV). ZYMFENTRA blocks the action of tumor necrosis factor-alpha (TNF-alpha), a protein that can be overproduced in response to certain diseases and cause the immune system to attack normal, healthy parts of the body.

ZYMFENTRA was approved by the FDA through the Biologics License Application (BLA) under the 351 (a) pathway of the Public Health Service Act (a "stand-alone" BLA). ZYMFENTRA is considered a new biologic with a first-approved subcutaneous administration form and thus will be under patent protection for its dosage form by 2037 and for its route of administration by 2040.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS and MALIGNANCY

SERIOUS INFECTIONS

Patients treated with TNF blockers, including ZYMFENTRA, are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue ZYMFENTRA if a patient develops a serious infection or sepsis.

Reported infections include:

- Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Test patients for latent tuberculosis before ZYMFENTRA use and during therapy. Initiate treatment for latent infection prior to ZYMFENTRA use.
- Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.
- Bacterial, viral and other infections due to opportunistic pathogens, including Legionella and Listeria.

Carefully consider the risks and benefits of treatment with ZYMFENTRA prior to initiating therapy in patients with chronic or recurrent infection.

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with ZYMFENTRA, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including infliximab products. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including infliximab products. These cases have had a very aggressive disease course and have been fatal. Almost all patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. The majority of reported cases have occurred in patients with Crohn's disease or ulcerative colitis and most were in young adult males.

Contraindications

- ZYMFENTRA is contraindicated in patients with a history of a severe hypersensitivity reaction to infliximab-dyyb, other infliximab products, any of the inactive ingredients in ZYMFENTRA, or any murine proteins. Reactions have included anaphylaxis.

Warnings and Precautions

- ***Serious infections:*** Avoid in patients with active infection. If infection develops, conduct a prompt/complete diagnostic workup appropriate for immunocompromised patients and initiate antimicrobials. If systemic illness develops in patients who reside or travel to regions where mycoses are endemic, consider empiric antifungals.
- ***Malignancies:*** Malignancies, including lymphoma, were greater in TNF-blocker-treated patients. Consider the higher risk of hepatosplenic T-cell lymphoma (HSTCL) with combination therapy versus increased risk of immunogenicity and hypersensitivity reactions with monotherapy.
- ***Hepatitis B virus (HBV) reactivation:*** Test for HBV infection before starting treatment. Monitor HBV carriers during and several months after therapy for active HBV infection. If reactivation occurs, stop ZYMFENTRA and begin anti-viral therapy.
- ***Hepatotoxicity:*** Severe hepatic reactions, some fatal or necessitating liver transplantation have

occurred in patients receiving infliximab products. Monitor hepatic enzymes and liver function tests every 3-4 months during treatment; investigate liver enzyme elevations and interrupt treatment if drug-induced liver injury is suspected. Instruct patients to seek immediate medical attention if symptoms develop.

- ***Congestive heart failure (CHF):*** New onset or worsening symptoms may occur. Avoid in patients with CHF. Monitor for new/worsening symptoms when administering ZYMFENTRA.
- ***Hematologic reactions:*** Advise patients to seek immediate medical attention if signs and symptoms of cytopenia develop; consider stopping if significant hematologic abnormalities develop.
- ***Hypersensitivity and other administration reactions:*** Serious hypersensitivity reactions, including anaphylaxis have occurred with intravenous formulations of infliximab; discontinue ZYMFENTRA and start appropriate therapy.
- ***Neurologic reactions:*** Exacerbation or new onset CNS demyelinating disorders may occur; consider discontinuation of ZYMFENTRA.
- ***Risk of infection with concurrent administration of other biological products:*** Concurrent use with other immunosuppressive biologics may increase risk of infection.
- ***Risk of additive immunosuppressive effects from prior biological products:*** Consider the half-life and mode of action of prior biologics.
- ***Autoimmunity:*** Formation of autoantibodies and development of lupus-like syndrome may occur; discontinue ZYMFENTRA if symptoms develop.
- ***Vaccinations and use of live vaccines/therapeutic infectious agents:*** Prior to initiating ZYMFENTRA bring patients up to date with vaccinations. Live vaccines or therapeutic infectious agents should not be given with ZYMFENTRA. A 6-month waiting period following birth is recommended before the administration of live vaccines to infants exposed *in utero* to infliximab.

Common Adverse Reactions (≥3%)

- ***Ulcerative Colitis:*** COVID-19, anemia, arthralgia, injection site reaction, increased alanine aminotransferase, and abdominal pain.
- ***Crohn's Disease:*** COVID-19, headache, upper respiratory tract infection, injection site reaction, diarrhea, increased blood creatine phosphokinase, arthralgia, increased alanine aminotransferase, hypertension, urinary tract infection, neutropenia, dizziness, and leukopenia.

Drug Interactions

- Concurrent use with immunosuppressive biologics used to treat UC and CD is not recommended due to risk of infection.
- Formation of CYP450 enzymes may be suppressed by increased levels of cytokines during chronic inflammation. ZYMFENTRA could normalize the formation of CYP450 enzymes potentially resulting in decreased exposure of CYP450 substrates and requiring dose adjustments.

Please see full Prescribing Information, including **BOXED WARNING**.

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